Section 5: 510(k) Summary

A. Applicant Tables

Category	Comments
Sponsor:	Medical Predictive Science Corporation 2246 Ivy Rd, Suite 17 Charlottesville, VA 22903 Tel: (800) 394 1625
Correspondent Contact Information:	William E King CEO Medical Predictive Sciences Corp. (434) 220 0714 (Direct) (240) 220 6098 (FAX) wking@mpsc.biz
Device Common Name:	Electrocardiograph, HRV Analysis System
Device Classification Number:	21 CFR 870.2340
Device Classification & Product Code:	Class II, 74 DPS
Device Proprietary Name:	HeRO 3.0

Predicate Device:	HeRO 2.0
Predicate Device Manufacturer:	Medical Predictive Sciences Corp.
Predicate Device Common Name:	HRV Analysis System
Predicate Device Premarket Notification #	K081473
Predicate Device Classification:	21 CFR 870.2340
Predicate Device Classification & Product Code:	Class II, DPS

B. Date Summary Prepared

June 8th, 2011

C. Description of Device

HeRO 3.0 is comprised of off-the-shelf Personal Computers (PC's) and special-purpose hardware capable of acquiring, storing, analyzing, and reporting ECG data from the cardiac monitoring real-time network. Data is acquired either on a special-purpose Data Acquisition Device (DAD) or via the physiological monitoring network. It is stored and analyzed on a HeRO Server or physiological monitor. Results of the analyses are reported on one or more Viewing Stations. The analysis algorithms identify Heart Rate Variability (HRV) patterns that reflect transient decelerations and/or reduced baseline variability.

D. Indications for Use

Identical to Predicate HeRO 2.0:
HeRO is intended to acquire, store, analyze, and report on ECG data collected from infants. HeRO is intended to be used under the direct supervision of a licensed health care practitioner in a hospital neonatal or pediatric ICU environment.

HeRO is intended to be used for the analysis of the variability in RR intervals (heart rate) and to report measurements of the variability of heart rate data (HRV). The HRV measurements reported by HeRO are specialized in nature, and intended to identify periods of transient decelerations and/or reduced baseline variability in the heart rate.

HeRO is intended to provide only specialized HRV measurements and is not intended to produce any interpretation of those measurements or any kind of diagnosis.

The specialized HRV measurements produced by HeRO have not been approved by the FDA for any specific clinical diagnosis.

HeRO acquires data from a user-supplied ECG monitor, and requires a user-supplied local area network.

E. Comparison to Predicate Device

The application HeRO 3.0 is identical to the predicate HeRO 2.0 in Intended Use, Indications for Use, technology (microprocessor-based), and algorithm for processing Heart Rate data to derive an index Score of Heart Rate Variability HRV).

The devices differ in that the graphical interface for the 3.0 can be produced in several languages, and the HRV can be displayed on the patient's bedside physiological monitor screen. Also, the HeRO 3.0 can accept digital input from a physiological monitor via its software interface or by being resident in the physiological monitor's server.

These changes do not raise new types of safety and effectiveness questions. All changes were fully developed and validated within a design control environment compliant with the FDA's Quality System Requirements.

F. Summary of Supporting Data

HeRO 3.0 was developed and is manufactured in accordance with 21CFR820 Quality System Regulations. The HeRO-specific hardware has been third-party tested in accordance with IEC 60601-1 and IEC 60601-1-2. The HeRO 3.0 System performance matches its product specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Medical Predictive Science Corporation
c/o Mr. William E King, CEO
2246 Ivy Rd, Suite 17
Charlottesville, VA 22903

JUL - 8 2011

Re: K111601
Trade/Device Name: HeRO 3.0
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Codes: DPS
Dated: June 8, 2011
Received: June 8, 2011

Dear Mr. King:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use Statement

510(k) Number (if known): K111601

Device Name: Medical Predictive Sciences Corporation, HeRO 3.0

Indications For Use:

HeRO is intended to acquire, store, analyze, and report on ECG data collected from infants. HeRO is intended to be used under the direct supervision of a licensed health care practitioner in a hospital neonatal or pediatric ICU environment.

HeRO is intended to be used for the analysis of the variability in RR intervals (heart rate) and to report measurements of the variability of heart rate data (HRV). The HRV measurements reported by HeRO are specialized in nature, and intended to identify periods of transient decelerations and/or reduced baseline variability in the heart rate.

HeRO is intended to provide only specialized HRV measurements and is not intended to produce any interpretation of those measurements or any kind of diagnosis.

The specialized HRV measurements produced by HeRO have not been approved by the FDA for any specific clinical diagnosis.

HeRO acquires data from a user-supplied ECG monitor, and requires a user-supplied local area network.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardio...
510(k) Number K111601